

### **REMARKS**

This is in response to the final Office Action mailed on July 21, 2009. A Request for Continued Examination is filed concurrently herewith. A Petition for a three-month extension of time is also filed concurrently herewith to extend the deadline for response from October 21, 2009, to January 21, 2010.

In the Office Action, claims 1-3 and 7 were rejected. With this Amendment, claim 1 is amended, and new claims 15-17 are added. All amendments and new claims are fully supported by the original specification and drawings. No new matter is added. Claims 4-6 and 8-14 were previously canceled. Claims 1-3, 7, and 15-17 are pending in the application. In light of the foregoing amendments and following remarks, Applicant respectfully requests advancement of this application to allowance.

### **Rejections Under 35 U.S.C. § 103**

At section 3 of the Office Action, claims 1-3, and 7 were rejected under §103(a) as being unpatentable over Phillips (U.S. Patent No. 6,565,513) in view of Nidorf et al. (J Am Coll Cardiol 1992; 19:983-8). Applicant respectfully traverses the rejection and the sufficiency of the rejection is not conceded. Claim 1 is amended herein to specify that the heart valve previously recited in claim 1 is the pulmonary valve. Reconsideration is requested because the invention recited in claim 1 would not have been obvious to a person of skill in the art at the time of the invention in view of Phillips and Nidorf.

In the rejection of claim 1, at page 3 of the Office Action, the examiner states that “[s]ince pulmonary annular diameter is also a cardiac dimension, it would have been obvious to one of ordinary skill in the art to follow the method of Nidorf et al. to find and use a single variable formula, similar to those in Table 1, to calculate the diameter of the pulmonary valve of a patient wherein the single variable is the patient’s height.”

Applicant respectfully disagrees. The methodology of Nidorf will not work effectively when attempting to calculate the pulmonary annular diameter as suggested by the examiner. Nidorf would suggest the utilization of standard two-dimensional echocardiography (see, page 983). However, as noted in the present application (page 3, line 23 – page 4, line 23), attempting to measure the pulmonary arterial diameter via echocardiography is extremely difficult due to the

orientation of the pulmonary artery within the human body. This leads to large errors in any measurement results. Without the ability to effectively measure the pulmonary arterial diameter, there is no way to utilize the method of Nidorf to calculate the single variable formula in question. There is no suggestion in Nidorf as to how this diameter can be otherwise calculated or how any formula relating the pulmonary valve dimensions to the patient's height can be calculated.

Taking cadaver measurements of the relationship between height and pulmonary artery diameter will also be unhelpful as the heart muscles are not under pressure in that state--and so any such measurement is likely to be in error.

In the preferred embodiment, the inventor has uncovered a relationship not previously evident that allows for calculation of the pulmonary arterial diameter by relating the flow velocity through the aortic diameter to the flow velocity through the pulmonary artery. Both of these flow velocities can be obtained from Doppler ultrasound measurements. In experiments conducted by the inventor, the flow ratio was found to be 1.126 (page 6, lines 6-8). Through utilization of this relationship, an accurate determination of the relationship between height and pulmonary arterial diameter can be derived.

The utilization of the flow velocity relationship is not taught or suggested by the Nidorf citation or by combining the disclosures of Nidorf and Phillips. Accordingly, Applicant respectfully requests reconsideration and allowance of claim 1, as well as claims 2-3 and 7 that ultimately depend therefrom.

In addition to the foregoing, Applicant respectfully repeats the arguments presented in Applicant's prior communications and does not otherwise concede the rejection, characterizations of the claims, and/or the characterizations of the cited references made in the Office Action.

#### **New Claims 15-17**

New claims 15-17 added with this Amendment and Response, which ultimately depend from claim 1, discussed above, and are therefore allowable for at least the same reasons as claim 1. Further, claims 15-17 also recite additional features that further distinguish the claims from the cited references. For example, claim 15 recites "wherein said correlation is determined

through the utilization of a first ratio of the relative speed of the flow velocity through the pulmonary artery and the flow velocity through the aortic annulus, and a second ratio of the patient's height to the aortic annulus diameter. Claim 16, which depends from claim 15, further recites "wherein the first ratio is substantially equal to 1.126." These features are neither taught nor suggested by the cited references. Claim 17 further recites that "measuring the velocity time integral or stroke distance of blood flowing from the heart of the patient via the pulmonary valve is performed with an ultrasonic transducer device." Accordingly, consideration and allowance of new claims 15-17 are respectfully requested.

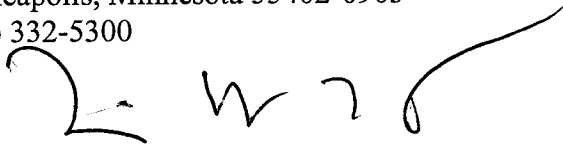
### Conclusion

In view of this Amendment and Response, Applicant respectfully requests a Notice of Allowance. There may be additional reasons that the pending subject matter is patentably distinct from the cited references in addition to those discussed herein. Applicant reserves the right to raise any such arguments in the future. If the Examiner believes that a telephone conference would advance the prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number listed below.

Respectfully submitted,

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